

Message

From: Post, Gloria [Gloria.Post@dep.nj.gov]
Sent: 6/19/2017 4:29:55 PM
To: Strynar, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a9910d5b38e471497bd875fd329a20a-Strynar, Mark]; Maddaloni, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b49225c65f43422ea68433b7058af1c0-Maddaloni, Mark]; Lindstrom, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=04bf7cf26aa44ce29763fbc1c1b2338e-Lindstrom, Andrew]
Subject: RE: NC DHHS GenX drinking water guidance value.
Attachments: Netherlands Public Health Agency evaluation of GenX.pdf

Mark, Mark, and Andy,

1. A retired colleague who was looking at this found an ECHA document which appears to be the source of the "Derived No Effect Level" (similar to a Reference Dose) of 0.01 mg/kg/day dose which led to a drinking water level of 70 ug/L using standard exposure assumptions (2 L per day, 70 kg, 20% Relative Source Contribution).

It is based on a NOAEL of 1 mg/kg/day from the chronic rat study with a total uncertainty factor of 100 (10 interspecies, 10 intraspecies).

These are the links to the ECHA documents:

FRD 902

EC# 700-242-3

CAS# 62037-80-3

<https://echa.europa.eu/registration-dossier/-/registered-dossier/2679>

Tox Summary

<https://echa.europa.eu/registration-dossier/-/registered-dossier/2679/7/1>

2. However, I noticed that The Netherlands (RIVM) document on GenX toxicology (attached) reports a lower NOAEL of 0.1 mg/kg/day from another study. And at least one of the mouse studies reviewed by them appears to report effects at a dose lower than 1 mg/kg/day.

http://www.rivm.nl/Documenten_en_publicaties/Wetenschappelijk/Rapporten/2016/december/Evaluation_of_substances_used_in_the_GenX_technology_by_Chemours_Dordrecht

RIVM derived a risk-based inhalation value based on oral toxicology data (sections 4.7.3 and 4.7.4, starting on numbered p. 36). **I am not "endorsing" this risk assessment – I have no comment on whether the basis of this value is sound or appropriate, but I did look at it to see how it is derived.**

It is based on an oral NOAEL of 0.1 mg/kg/day from a rat study. They used a total uncertainty factor of 1188 (on p. 39) which accounts for the expected longer half-life in humans than rodents, as well as interspecies toxicodynamic differences and intraspecies differences. They converted to an inhalation dose, but if that conversion it is left out, the oral "Reference Dose" (or whatever The Netherlands term for this is) would be 0.084 ug/kg/day or 84 ng/kg/day.

Applying the default drinking water assumptions mentioned above (2 L per day, 70 kg, 20% Relative Source Contribution) would give a drinking water value of about 600 ng/L.

If minimal or no exposure from non-drinking is assumed, the maximum Relative Source Contribution factor that is recommended is 80%. Using an 80% RSC, the drinking water value would be 4-fold higher, or about 2400 ng/L (2.4 ppb).

Thanks
Gloria

From: Strynar, Mark [mailto:Strynar.Mark@epa.gov]
Sent: Wednesday, June 14, 2017 7:25 AM
To: Maddaloni, Mark <Maddaloni.Mark@epa.gov>; Lindstrom, Andrew <Lindstrom.Andrew@epa.gov>
Cc: Post, Gloria <Gloria.Post@dep.nj.gov>
Subject: RE: NC DHHS GenX drinking water guidance value.

Do any of you believe this posed value? The story says based on a rat study the NOEL would be about 70,000 ng/L.

Mark

From: Maddaloni, Mark
Sent: Tuesday, June 13, 2017 3:59 PM
To: Strynar, Mark <Strynar.Mark@epa.gov>; Lindstrom, Andrew <Lindstrom.Andrew@epa.gov>
Subject: FW: NC DHHS GenX drinking water guidance value.

fyi

From: Post, Gloria [mailto:Gloria.Post@dep.nj.gov]
Sent: Tuesday, June 13, 2017 3:56 PM
To: Maddaloni, Mark <Maddaloni.Mark@epa.gov>
Subject: NC DHHS GenX drinking water guidance value.

70 ppb. Their statement is linked from the news story

<http://www.wwaytv3.com/2017/06/13/genx-water-cape-fear-river/>

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